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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/049,968      | 02/13/2002  | Heinrich Wieland     | 70301/56970         | 6225             |

21874 7590 12/17/2003

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EXAMINER

WEBER, JON P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1651     |              |

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/049,968

Applicant(s)

WIELAND ET AL.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 26-44 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☒ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: .

***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 13 August 1999. The IB has not provided a certified copy of the German application as required by 35 U.S.C. 119(b). Applicants' assistance is requested.

***Claims***

The numbering of claims in the preliminary amendment filed 13 February 2002 is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 26 (second instance) to 50 have been renumbered 27-51.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 27-40, drawn to a method of restoring collagen by administering a substance which inhibits the production or effect of estrogens.

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Group II, claim(s) 41, drawn to a method of restoring collagen and of treating myocardial or brain infarctions.

Group III, claim(s) 42, drawn to a method of restoring collagen and of treating osteoporosis.

Group IV, claim(s) 43, drawn to a method of restoring collagen and of treating arteriosclerosis.

Group V, claim(s) 44, drawn to a method of restoring collagen and of treating urinary incontinence.

Group VI, claim(s) 45, drawn to a method of restoring collagen and of treating excessive production of glucocorticoids.

Group VII, claim(s) 46, drawn to a method for treating decrease hair growth.

Group VIII, claim(s) 47, drawn to a method for treating wrinkles, etc.

Group IX, claim(s) 48, drawn to a method of treating effects of sun exposure to the skin.

Group X, claim(s) 49, drawn to a composition comprising a first compound that inhibits the production or effects of estrogens and a second compound that inhibits the production or effects of dihydroxytestosterone.

Group XI, claim(s) 50, drawn to a composition comprising an aromatase inhibitor and a 5- $\alpha$ -reductase inhibitor.

Group XII, claim(s) 51, drawn to a composition comprising a compound that inhibits both of (1) the production or effects of estrogens, and (2) the production or effects of dihydroxytestosterone.

Group XIII, claim(s) 52, drawn to a composition comprising a compound that inhibits both (1) aromatase and (2) 5- $\alpha$ -reductase.

The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claims do not share a special technical feature. Some of the Groups share a technical feature: a substance that inhibits the production or effects of estrogens, but not all of the Groups do. Further, compounds that inhibit the production or effects of estrogens are alleged to be aromatase and/or 5- $\alpha$ -reductase inhibitors. Such compounds are known in the art, see EP 776,661 and EP 684,235, cited in the IDS, for example. Accordingly, these inhibitors cannot form the basis of unity of invention because they do not provide a contribution over the art.

Each of Groups I-IX is drawn to different methods having different results and using different compositions.

Each of Groups X-XIII is drawn to different compositions having different effects and results.

### *Species*

Claims 27-52 are generic to a plurality of disclosed patentably distinct species comprising

- 1) compounds that inhibit estrogen production – relevant to Groups I-IX and XII
- 2) compounds that inhibit the effects of estrogens – relevant to Groups I-IX and XII
- 3) compounds that inhibits the production dihydroxytestosterone – relevant to Group I, claim 24, and Groups X and XII.

4) compounds that inhibits the effects of dihydroxytestosterone – relevant to Group I, claim 24, and Groups X and XII.

5) 5- $\alpha$ -reductase inhibitors – relevant to Group I, claims 35-36, and Groups XI and XIII

6) compounds that inhibit both of (1) the production or effects of estrogens, and (2) the production or effects of dihydroxytestosterone – relevant to Group XII

7) compounds that inhibit both of (1) aromatase and (2) 5- $\alpha$ -reductase – relevant to Group XIII.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of compound from one of each species relevant to the particular Group elected, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

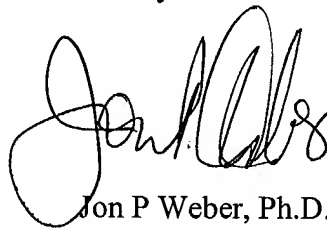
This is an election/restriction only.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

My new Office room number will be Rem-03A45 and my new Office phone number will be 571-272-0925 after 15 January 2004.

A handwritten signature in black ink, appearing to read 'Jon P Weber', with a long, sweeping horizontal line extending to the right.

Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
12 December 2003